REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated May 16, 2006.

Claims 42-43, 73 and 91-93 are pending in the application. Claims 62, 63 and 65, which are withdrawn from consideration, have been canceled without prejudice to further prosecution. Claims 42, 43, 73, 91, 92 and 93 have been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention.

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Claim Amendments

Claims 42, 43, 73, 91, 92 and 93 have been amended. Support for the newly presented and amended claims can be found generally through Applicants' Specification.

In particular, Claim 42 has been amended to recite an antibody capable of binding oligodendrocytes and capable of inducing remyelination. IgM monomers and active Fab, Fab', $F(ab')_2$ or Fv fragments are now recited in the claim for clarification. Support for the term "IgM monomers" can be found in the Specification including at page 192 line 10 and page 210 line 20. Support for "Fab, Fab', $F(ab')_2$ or Fv fragments" is found in the Specification including at page 52 line 28, page 53 line 6 and pages 208-211 (Example 23). Recombinant antibodies are characterized as having a heavy chain comprising a heavy chain variable region sequence of SEQ ID NO:7 and a light chain comprising a light chain variable region sequence of SEQ ID NO:9.

Claim 43 is above amended to recite an antibody capable of binding oligodendrocytes and capable of inducing remyelination having a heavy chain comprising a heavy chain variable region sequence of SEQ ID NO:7 and a light chain comprising a light chain variable region sequence of SEQ ID NO:9.

Claim 73 is amended to recite an antibody polypeptide capable of binding

oligodendrocytes and capable of inducing remyelination produced by introducing a vector comprising a DNA sequence encoding an antibody polypeptide having a heavy chain sequence comprising the amino acid sequence of SEQ ID NO:7 and a light chain comprising the amino acid sequence of SEQ ID NO:9. Support for the claim amendments are found in the Specification including at page 9 lines 17-21, page 185 lines 21-23 and page 190.

Claim 91 is amended to recite an antibody capable of binding oligodendrocytes and capable of inducing remyelination, having a heavy and light chain with heavy chain comprising the sequence set out in SEQ ID NO:7 and light chain comprising the sequence set out in SEQ ID NO:9. Active Fab, Fab', $F(ab')_2$ or Fv fragments capable of binding oligodendrocytes and capable of inducing remyelination are now recited in the claim for clarification. Support for "Fab, Fab', $F(ab')_2$ or Fv fragments" is found in the Specification including at page 52 line 28, page 53 line 6 and pages 208-211 (Example 23).

Claim 92 has been amended to recite an antibody capable of binding oligodendrocytes and capable of inducing remyelination, having a heavy and light chain with heavy chain comprising a heavy chain variable region sequence as set out in SEQ ID NO:7.

Claim 93 has been amended to recite an antibody capable of binding oligodendrocytes and capable of inducing remyelination, having a heavy and light chain with light chain comprising a light chain variable region sequence as set out in SEQ ID NO:9.

Claim Rejections - 35 USC §112, First Paragraph

The Examiner has rejected claims 42, 73, and 91-93 under 35 U.S.C. 112, first paragraph, because the Examiner asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most connected, to make and use the invention commensurate in scope with these claims. The Examiner remarks that the specification, while being enabling for the isolated antibody sHIgM22 and fragments thereof which bind to oligodendrocytes and induce remyelination, does not reasonably provide enablement for monomers which do not bind oligodendrocytes, or for all recombinant antibodies derived from sHIgM22, or for antibodies or polypeptides comprising either SEQ ID NO:7 or 9 which do not bind oligodendrocytes, or for antibodies which bind oligodendrocytes but do not induce remyelination. Applicants respectfully disagree. While some experimentation to make and test

the antibodies, monomers and fragments as claimed would be necessary, such experimentation would utilize well known and standard skills and would not constitute undue experimentation. Without prejudice to any future prosecution, Applicants have above amended claims 42, 73 and 91-93 to recite that the antibody or pharmaceutical composition be capable of binding oligodendrocytes and be capable of inducing remyelination. Applicants have also above clarified the monomer and fragment recitations in claims 42 and 91. Further, Applicants have above clarified claim 73 to recite an antibody polypeptide produced by a DNA sequence encoding an antibody polypeptide having a heavy and light chain. The Specification enables the claimed antibodies and compositions of mAb sHIgM22 (LYM 22), monomers thereof, active fragments thereof, and recombinant antibodies derived therefrom. The claims as presented include Fab, Fab', $F(ab')_2$ or Fv fragments which are capable of binding oligodendrocytes and capable of inducing remyelination, a capacities and activities which can readily be assayed and determined. The Specification provides ample teaching, in addition to the knowledge and significant skill of the skilled artisan, and describes IgM monomers, active Fab, Fab', $F(ab')_2$ and Fv fragments and active recombinant antibodies. In fact, the Specification describes the construction or generation of these monomers, fragments and recombinant antibodies and the assessment of their activity including in Example 9, Example 18, Example 20, Example 21 and Example 23. Thus, the Specification provides a remarkable amount of teaching and support for each and any of the particular claimed sHIgM22 antibody, monomers thereof, active fragments thereof, and recombinant antibodies derived therefrom. Contrary to the Examiner's assertion Applicants submit that the claims as presented are enabled and it would not constitute undue experimentation for the skilled artisan to make and use the invention as claimed.

Claims 42-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner has determined that in order for the skilled artisan to make the claimed antibodies, the artisan must have access to the hybridoma that produces the antibodies. Applicants respectfully disagree. Claim 42 as above amended and presented refers to and recites antibodies having a heavy chain comprising a heavy chain variable region sequence of SEQ ID NO:7 and a light chain comprising a light chain variable region sequence of SEQ ID NO:9, IgM monomers or Fab, Fab', $F(ab')_2$ and Fv fragments thereof. The claims as now pending are directed to antibodies or pharmaceutical compositions comprising

particular and specific heavy and/or light chain sequences. It would clearly be possible for one of skill in the art to make the claimed antibody or composition in the absence of the hybridoma that produces it.

The Examiner has rejected claims 42 and 91 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully disagree and would assert that the claims as presented meet the written description requirements. The claims as above amended recite and require a structure and a particular activity. The Specification, as noted above, describes each of sHIgM22 antibody comprising the recited sequences, IgM monomers thereof, active Fab, Fab', $F(ab')_2$ and Fv fragments thereof, and recombinant antibodies derived therefrom, disclosing a reasonable number of members and supporting the scope of the claimed genus. Applicants asserts that the written description requirement for the claims is clearly met.

In view of the foregoing remarks, Applicants submit that the Examiner's rejections under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

Claim Rejections - 35 USC § 102

Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by PIR_79 database accession number S05270, sequence last revised 30 June 1992. Applicants respectfully disagree and submit that PIR_79 database accession number S05270 does not anticipate the claimed compositions and antibodies.

Claim 42 has been amended to recite an antibody capable of binding oligodendrocytes and capable of inducing remyelination having a heavy chain comprising a heavy chain variable region sequence of SEQ ID NO:7 and a light chain comprising a light chain variable region sequence of SEQ ID NO:9. Claim 42 is also directed to IgM monomers, particular fragments and recombinant antibodies having a heavy chain comprising a heavy chain variable region sequence of SEQ ID NO:7 and a light chain comprising a light chain variable region sequence of SEQ ID NO:9.

Anticipation is a question of fact. To anticipate a claim a prior art reference must teach or suggest each and every limitation of the claim. The cited PIR_79 database accession number S05270 reference relates to a light chain sequence of an absolutely distinct antibody, antibody

secreted from 4G12 hybridoma cells with broad reactivity to malignant tumor cells, particularly lung carcinomas. The PIR_79 reference does not teach, describe or suggest the specific sHIgM22 antibody or active fragments thereof particularly as now claimed.

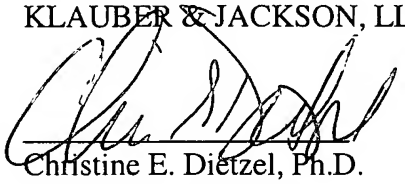
In view of the foregoing amendments and remarks, Applicants submit that the Examiner's 35 U.S.C. 102 rejection is obviated and should be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

KLAUBER & JACKSON, LLC.



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